

PROPOFOL SANDOZ

Propofol

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about this medicine.

It does not contain all the available information. It does not take the place of talking to your doctor or anaesthetist.

All medicines have risks and benefits. Your doctor or anaesthetist has weighed the risks of you being given Propofol Sandoz against the benefits it is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor or anaesthetist.

Keep this leaflet after your operation or hospital stay.

You may need to read it again.

What Propofol Sandoz is used for

General anaesthesia

Propofol Sandoz contains propofol, which is used as a short-acting general anaesthetic in adults, and children aged 3 years or older.

A general anaesthetic is a medicine which produces general anaesthesia. Propofol Sandoz is short-acting, which means that patients go to sleep quickly, usually within 30 seconds of receiving the medication, but then wake up quickly as it wears off.

Propofol Sandoz can be used for very short operations when only one injection is needed.

Propofol Sandoz can be used throughout longer operations if more

is given as repeated doses (maintenance anaesthesia).

Propofol Sandoz can also be used to start off an anaesthetic (induction anaesthesia). This means the anaesthetist may change over to a gas anaesthetic once sleep is induced.

Sedation

Propofol Sandoz can be given to adults and adolescents over 16 years of age in lower doses if they need to be sedated or sleepy, but do not need the heavy sleep of anaesthesia. This type of sedation may be required during certain tests or procedures.

Propofol Sandoz can also be given in intensive care wards for adults and adolescents over 16 years of age who are being ventilated (on a breathing machine) to keep them sedated.

Ask your doctor or anaesthetist if you have any questions about why this medicine has been prescribed for you. Your doctor or anaesthetist may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 3 years for general anaesthesia. This medicine must not be used for children 16 years of age and under for sedation during tests or procedures, or for sedation in the intensive care ward.

Before you are given Propofol Sandoz

When you must not be given it

You must not be given Propofol Sandoz if you have an allergy to:

- any medicine containing propofol;
- any of the other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Before you are given it

Tell your doctor or anaesthetist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or anaesthetist if you have or have had any of the following medical conditions:

- epilepsy (fits or convulsions)
- heart disease
- respiratory (breathing) problems
- liver or kidney disease
- very high blood fat levels or disorders of fat metabolism (this warning applies to very rare conditions, not the more common high blood cholesterol)
- general debility for some time (feebleness, weakness or loss of strength).

Tell your doctor or anaesthetist if you are pregnant or if you intend to become pregnant or are breast-feeding. It may be necessary to defer

an operation or procedure, or use different anaesthetics if you are pregnant or breast feeding.

Propofol Sandoz is not recommended for use during pregnancy or breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor or anaesthetist about any of the above, tell them before you are given Propofol Sandoz.

Taking other medicines

Tell your doctor, anaesthetist or pharmacist if you are taking or using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and propofol may interfere with each other. These include:

- strong pain relievers;
- medicines used to produce calmness or to help you to sleep;
- some medicines used to treat anxiety;
- some medicines used to treat epilepsy such as barbiturates.

Your doctor, anaesthetist or pharmacist may have information on medicines to be careful with or avoid when you are given this medicine.

How Propofol Sandoz is given

How much is given

Your doctor or anaesthetist will decide how much Propofol Sandoz you are to be given. This will depend on your age and other factors such as your weight and the duration of your procedure. The dose will be adjusted to keep you at the right depth of sleep or sedation. The dose of Propofol Sandoz needed for sedation is less than that needed for anaesthesia.

How it is given

Propofol Sandoz is given by an injection into a vein, usually in the forearm or the back of the hand. It must only be given by a doctor or anaesthetist. Each vial is used for one dose in one patient only. Any remaining contents must be discarded after each dose.

Overdose

As Propofol Sandoz is given to you under the supervision of your doctor or anaesthetist, it is very unlikely that you will receive too much. Your doctor or anaesthetist has information on how to recognise and treat an overdose.

Ask your doctor or anaesthetist if you have any concerns.

While you are being given Propofol Sandoz

Things to be careful of

Do not drive a car or operate machinery for at least one day after you have been given Propofol Sandoz.

As with other anaesthetics, Propofol Sandoz may cause impairment of skilled tasks, such as driving or operating machinery, for some time after you have been given it.

Make sure you know how you react to Propofol Sandoz before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy or dizzy.

Ask your doctor when you can return to work involving driving, or operating machinery or heavy equipment.

Side Effects

This medicine helps provide anaesthesia or sedation for most people, but it may have unwanted

side effects in a few people. Some of the unwanted effects of Propofol Sandoz are the result of sleep being too light or too deep. Your anaesthetist will reduce the dose for Propofol Sandoz if your blood pressure is too low, or if you need help breathing. Other medicines may be needed if your heart rate becomes too slow or irregular.

Tell your doctor or anaesthetist as soon as possible if you do not feel well after you have been given Propofol Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or anaesthetist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- feeling like fainting
- having difficulty breathing
- pain, heat or tingling at the injection site
- flushing of the skin
- dizziness
- nausea or vomiting, cough, headache, shivering, restlessness or mood changes when you are waking up from the anaesthetic
- hiccuping or stopping breathing very briefly
- feeling sick or vomiting
- cough
- elation or euphoria.

The above list includes the more common side effects of your medicine. They are usually mild and short lived.

Tell your doctor or a nurse immediately if you notice any of the following:

- slow, fast or irregular heart beat;
- convulsions (fitting);
- signs of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin;
- muscle pain;
- severe pain in the upper stomach;
- temporary paralysis or weakness of the muscles.

The above list includes serious side effects. These side effects are rare.

Some of the side effects of Propofol Sandoz may occur whilst you are asleep or sedated. Your doctor or anaesthetist is trained to manage these reactions in the unlikely event that they occur. For example, if you are sleeping too deeply and your blood pressure is too low or you need help breathing, your anaesthetist may reduce the dose of Propofol Sandoz. If your sleep is too light and you move or wriggle a bit, the dose may be increased. If your heart rate becomes too slow or irregular other medicines may be needed.

Tell your doctor or anaesthetist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After using Propofol Sandoz

Storage

Propofol Sandoz will be stored in the pharmacy or on the ward. Propofol Sandoz is kept in a cool dry place where the temperature stays below 25°C.

Any unused Propofol Sandoz from the opened vial will be discarded.

Product Description

What it looks like

Propofol Sandoz is a milky, white liquid in a clear glass vial with an aluminium and violet plastic cap.

It is available in 20 mL, 50 mL and 100 mL vials.

Ingredients

Active ingredients:

- propofol 10 mg/mL.

Inactive ingredients:

- Soya oil
- Glycerol
- Lecithin egg
- Sodium oleate
- Water for injection

Propofol Sandoz 200 mg/20 mL ampoules come in packs of 5's.

Propofol Sandoz 500 mg/50 mL and 1000 mg/100mL vials come individually.

Propofol Sandoz does not contain lactose, sucrose, gluten, tartrazine or other azo dyes.

Supplier

Sandoz Pty Ltd

ABN 60 075 449 553

54 Waterloo Road

Macquarie Park NSW 2113

Australia

Tel: 1800 726 369

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Australian Register Numbers

Propofol Sandoz, Propofol 200 mg/20ml emulsion for Injection, AUST R: 148870

Propofol Sandoz, Propofol 500 mg/50ml emulsion for Injection, AUST R: 148871

Propofol Sandoz, Propofol 1000 mg/100ml emulsion for Injection, AUST R: 148872